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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,846	06/06/2002	John Carter	3920-0110P	5250
2292	7590	09/25/2007	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			CHOI, FRANK I	
PO BOX 747			ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22040-0747			1616	
NOTIFICATION DATE		DELIVERY MODE		
09/25/2007		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/089,846	CARTER, JOHN	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 6/19/2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 89-102, 104-106, 108, 124, 125, 127-130, 132-135, 137-147 and 149-164 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 89-96, 98, 99, 101, 102, 104-106, 108, 124, 125, 127-130, 132-135, 139-147, 149 and 152-164 is/are rejected.
- 7) Claim(s) 97, 100, 137, 138, 150 and 151 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

The Examiner withdraws the election of species requirement. As such, claims 89-102, 104-106, 108,124,125,127-130, 132-135,137-147, 149-164 will be prosecuted accordingly.

Claim Objections

Claims 97,100,137,138,150,151 are objected to as being dependent on a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 89-96,98,99,101,102, 104-106, 108,124,125,127-130, 132-135,139-147, 149,152-164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US Pat. 5,654,011) in view of Riley et al. (US Pat. 5,948,443), Klampfer et al., Wawretscheck et al. (US Pat. 4,061,741), DE 2457424, Herschler (US Pat. 4,514,421), Herschler (US Pat. 4,616,039) and Menon et al..

Jackson et al. disclose compositions and methods for providing dietary supplements to meet the needs of pre-perimenopausal women, including pregnant women, and to reduce the risk of cancer comprising copper, manganese, zinc, iron and vitamin C (Column 2, lines 25-51, Column 4, lines 13-23, Column 8, lines 30-68).

Riley et al. discloses a composition and method of reducing the risk of cancer by providing dietary supplements to women which comprise aspirin or bioequivalent forms, such as

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salicylic acid or other salicylates, iron, zinc, manganese, copper and Vitamin C (Column 9, lines 30-55, Column 21, lines 7-63, Table III).

Klampfer et al. disclose that nonsteroidal anti-inflammatory agents are known for their chemopreventive activity and that sodium salicylate and aspirin induce apoptosis or leukemia cells (See pages 2386, 2393).

Wawretschek et al. disclose that the analgesic efficiency of sodium salicylate can be reinforced by combining with a salt of orotic acid (Claims 10, 30,39).

DE 2457424 disclose that zinc orotate is effective against cancer, with zinc being the active component and the orotate anion increasing bioavailability of the zinc (pages 1-3).

Hershler (US Pat. 4,514,421) disclose that administration of methylsulfonylmethane (MSM) and ascorbic acid and that administration of MSM resulted in reduction of tumor mass (Column 12, lines 7-47).

Hershler (US Pat. 4,616,039) disclose that methylsulfonylmethane is an assimilable source of sulfur (Abstract).

Memnon et al. disclose that vitamin C inhibits tumor growth (Abstract).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of copper orotate, manganese orotate, iron orotate, sodium salicylate, a source of assimilable sulfur and vitamin C. However, the prior art amply suggests the same as the prior art discloses dietary supplements which combine various nutrients, such as copper, manganese, vitamin C with salicylates for use in women and reducing the risk of cancer, the combination of sodium salicylate and salts of orotate to increase the efficacy of the sodium salicylate, the use of copper, manganese, iron and vitamin C for use in pregnant women and

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reducing the risk of cancer, MSM for treatment of cancer. Further, the prior art disclose and/or suggest that zinc orotate, ascorbic acid and sodium salicylate (NSAIDS) are effective neoplastic diseases. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art by providing the copper, iron, zinc and manganese as salts of orotate so as to increase the efficacy of the sodium salicylate and to combine copper, iron, zinc and manganese with sodium salicylate and vitamin C with the expectation that the composition would be suitable for use in pregnant women and for treatment of cancer, to further add MSM as it is effective in treating cancer.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Action (1/19/2007) and moot in light of the new grounds of rejection above.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Further, with respect to the Applicant's arguments as to motivation, the Supreme Court in *KSR v. Teleflex* has held that motivation is not a required element of the prima facie case of obviousness. The mere fact that one or more of the references do not disclose treatment of

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cancer or all of the components in a single reference does not make the claimed invention non-obvious. Although the claims require that the composition have an anti-neoplastic effect, there is no requirement that all the components have an anti-neoplastic effect so long as the composition has an anti-neoplastic effect. Since the prior art discloses and/or suggests that ascorbic acid, zinc, sodium salicylate and methylsulfonylmethane has anti-neoplastic effects, one of ordinary skill in the art would expect that a combination of the same with minerals such as copper, manganese and iron, including salts of the same with orotate as the anion, would have anti-neoplastic effects. Since the Applicant has not provided evidence of the criticality of each element in the combination of pharmacologically active components, it would have been well within the skill of one of ordinary skill in the art to add copper, iron and manganese to the combination of ascorbic acid, zinc, sodium salicylate and methylsulfonylmethane, with the expectation that the combination without other pharmaceutically active components would be effective as antineoplastic composition and that the copper, iron and manganese would provide nutrients to the cancer patient. Further, since the prior art recognizes that the zinc in the zinc orotate is the active component, it would have been well within the skill of one of ordinary skill in the art to use other pharmaceutically acceptable anions as desired.

As such, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
September 17, 2007



Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600